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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

JOSE CHUNG LUO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. SPECTRUM PHARMACEUTICALS, INC., et al., Defendants.	No. 2:21-cv-01612-CDS-BNW CLASS ACTION LEAD PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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STATUTES, RULES, AND REGULATIONS

I. SUMMARY OF THE ARGUMENT

In the SAC, Lead Plaintiff International Trading Group, Inc. substantially fortified its allegations from the First Amended Consolidated Class Action Complaint (ECF 46) (the "FAC").[1] It added significant detail concerning Defendants' false and misleading statements, laying out the precise material information Defendants failed to accurately describe or disclose to investors. It bolstered the scienter allegations by describing the dates when each speaking Defendant learned information contradicting his public statements. It supplemented these allegations by adding timelines demonstrating the correlation between Defendants' knowledge, their statements, and their suspicious trading activity and corporate financings. SAC, Apps. A-D. And it added inside accounts from confidential witnesses ("CWs") who confirmed Defendants' real-time access to data, which Defendants previously denied. These allegations, in addition to the already-strong allegations from the FAC, sufficiently plead a securities-fraud claim.

Spectrum was a small pharmaceutical company with only two experimental products, Pozi and Rolontis, neither of which earned revenue. During the Class Period, Spectrum burned tens of millions of dollars per quarter as it attempted to usher one drug or the other through clinical trials and toward FDA approval and profitability. With quickly depleting cash stores, Spectrum was forced to rely on the investing public for liquidity. The Company engaged in repeated financings and public offerings, the success of which depended on a positive public perception. Defendants knew they could not afford bad news. Accordingly, when Pozi failed multiple clinical trials and the Rolontis manufacturing plant failed multiple mock inspections, Defendants chose not to disclose that information. Instead, they turned to fraud.

Leading into the Pozi MD Anderson trial, Defendants knew the FDA would measure Pozi's efficacy against the best available therapy already on the market, which had a 22.9% response rate (ORR) among patients with Non-Small Cell Lung Cancer ("NSCLC"). The FDA informed Defendants that it would not approve Pozi unless the drug demonstrated at least a 30% response rate

[1] All capitalized terms not defined herein have the same meaning as set forth in the Second Amended Consolidated Class Action Complaint (ECF 93) ("SAC"). Additionally, all "¶_" or "¶¶_" citations are to the SAC and unless otherwise noted, citations are omitted and emphasis is added.

(or ORR). Nevertheless, CEO Turgeon and COO Riga falsely described a lower bar to investors, claiming "other therapies only have a 6% to 8% response rate," so a "20% to 30% response rate" would warrant FDA approval. Investment analysts parroted this false lower targets to the market.

During the failed ZENITH20 trial, Defendants had "open" access to fully confirmed safety and efficacy results showing that the trial had failed to meet the FDA's "pre-specified" 30% ORR threshold for approval. Two CWs provided corroborating accounts of Defendants' access to and use of the clinical trial data from a Spectrum-controlled database, detailing how Defendants had access to "final conclusions" from radiologists and clinicians about Pozi's poor efficacy and debilitating adverse event ("AE") profile. Despite knowledge of Pozi's failure, Defendants claimed the drug was in a "pole position" among competing cancer drugs, touted stale positive results, and minimized the AEs Pozi patients experienced.

For Rolontis, when the FDA rejected Spectrum's first BLA as inadequate, Turgeon falsely claimed the Company "voluntarily" withdrew the application for "administrative" reasons. And during the pendency of the second BLA, while Spectrum waited for the FDA to schedule its inspection of the manufacturing plant in South Korea, Turgeon claimed the Company was "absolutely ready for this inspection" because they had been through "multiple mock inspections." But, according to a CW, Turgeon failed to disclose that Spectrum had actually failed those inspections and lacked control over the facility to implement changes necessary to bring it into compliance. Ultimately, the FDA inspected the facility and found rampant deficiencies.

The SAC also describes how the Individual Defendants capitalized on the information imbalance they created with investors by selling substantial portions of their shares at opportune times. In the most telling example, Turgeon sold 45% of his holdings in two large sales that ended on December 16, 2020 – ***just six days before the Company finally announced the failure of Cohort 3 in the ZENITH20 trial***.

Defendants attempt to discredit these allegations, often reaching far outside the SAC to provide "context" for the alleged misstatements. For the MD Anderson trial, they claim investors "would have known" that their descriptions of the efficacy of competing drugs referred only to a certain subset of competing drugs, even though Defendants never provided that clarity. They claim

ZENITH20 data was not available to them or they did not look at it, even though Lebel admitted: "It's an open trial, so obviously, we're looking at the data." They claim they disclosed the existence of Rolontis mock inspections, but concede they did not disclose the failure of those inspections. They claim Turgeon's massive sell-off of nearly half his shares was actually merely a non-discretionary "tax withholding" or SEC Rule 10b5-1 sale, affirmative defenses that are not ripe for resolution on a motion to dismiss.

Defendants' unlikely interpretations of Plaintiff's allegations do not justify dismissal at this early stage. Their motion should be denied.

II. LEGAL AUTHORITY

When deciding a Rule 12(b)(6) motion to dismiss, the Court must "consider the complaint in its entirety" and "accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007); *see also No. 84 Emp'r-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003). "[A] district court ruling on a motion to dismiss is not sitting as a trier of fact," and "so long as the plaintiff alleges facts to support a theory that is not facially implausible, the court's skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be rejected on evidentiary grounds." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1057 (9th Cir. 2008). Although the Private Securities Litigation Reform Act of 1995 ("PSLRA") elevated the pleading standard that applies to private securities fraud class action complaints, "'courts must be careful not to set the hurdles so high that even meritorious actions cannot survive a motion to dismiss.'" *Roberti v. OSI Sys., Inc.*, 2015 WL 1985562, at *6 (C.D. Cal. Feb. 27, 2015). Thus, at the pleading stage a plaintiff "need only allege 'enough facts to state a claim to relief that is plausible on its face.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 n.12 (2011). "A complaint should not be dismissed unless it appears beyond a doubt that the plaintiff cannot prove any set of facts in support of the claim that would entitle him or her to relief." *Am. W.*, 320 F.3d at 931.

To allege a violation of §10(b) of the Securities Exchange Act of 1934, six elements must be pleaded: "'(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4)

reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 460-61 (2013). Here, Defendants challenge only the allegations pertaining to falsity and scienter.

Falsity. "'"[T]he disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers."'" *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2008); *see also Greenapple v. Detroit Edison Co.*, 618 F.2d 198, 205 (2d Cir. 1980) (where method of presentation or "gloss" placed on information obscures or distorts significance of material facts, it is misleading). And "'once defendants cho[o]se to tout' positive information to the market, 'they [are] bound to do so in a manner that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016) (alterations in original).

"[A] pleading is sufficient under Rule 9(b) if it identifies 'the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations.'" *Gottreich v. S.F. Inv. Corp.*, 552 F.2d 866 (9th Cir. 1977). "For its claims grounded in fraud, the SAC must allege the 'who, what, where, when, and how' of the fraudulent conduct." *Daniels Fam. 2001 Revocable Tr. v. Las Vegas Sands Corp.*, 2024 WL 21971, at *4 (D. Nev. Jan. 2, 2024) (Silva, J.).

> Whether a statement is misleading and whether adverse facts were adequately disclosed are generally questions that should be left to the trier of fact. "[O]nly if the adequacy of the disclosure or the materiality of the statement is 'so obvious that reasonable minds [could] not differ' are these issues 'appropriately resolved as a matter of law.'"

In re Syntex Corp. Sec. Litig., 95 F.3d 922, 926 (9th Cir. 1996) (alterations in original).

Scienter. To satisfy the scienter requirement, a complaint must allege that defendants made false or misleading statements either intentionally or with deliberate recklessness. 15 U.S.C. §78u-4(b)(2); *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008). "'An actor is deliberately reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort.'" *Shenwick v. Twitter, Inc.*, 282 F. Supp. 3d 1115, 1134 (N.D. Cal. 2017).

"[T]he ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity." *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010). The allegations that support falsity also give rise to a strong inference of scienter against all Defendants. *See, e.g.*, *Smilovits v. First Solar Inc.*, 119 F. Supp. 3d 978, 1000 (D. Ariz. 2015) (analyzing falsity and scienter together because "[t]hese elements are closely intertwined and dependent upon similar facts"), *aff'd sub nom. Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750 (9th Cir. 2018).

Courts must also consider "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23. A "'strong inference'" is one that a reasonable person would deem "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. In other words, "if two possible inferences – one fraudulent and the other nonfraudulent – are equally compelling, a plaintiff has demonstrated a strong inference of scienter." *ESG Cap. Partners, LP v. Stratos*, 828 F.3d 1023, 1033 (9th Cir. 2016).

III. ARGUMENT

A. Plaintiff Pled Misstatements During the Pozi MD Anderson Trial

In the SAC, and the timelines attached to it, Plaintiff describes with particularity """the circumstances constituting fraud,""" including the negative information Defendants received, when they received it, the statements they made contrary to that information, and why those statements materially misled investors. *See Daniels*, 2024 WL 21971, at *4 (Silva, J.).

1. Defendants Misled Investors About Existing Treatments

Prior to launch of the MD Anderson trial in March 2017, Spectrum met with the FDA and developed a protocol that "compared Pozi to the best existing therapy for NSCLC, which had 22.9% ORR." ¶¶78, 92, 113, 169, 173. During these meetings, Defendants learned the FDA required Pozi to hit an ORR of at least 30% for approval, and at greater than 43% for a fast-track route to approval, called Breakthrough Therapy Designation ("BTD"). ¶¶86-88, 92, 169, 173, 176. Plaintiff supported its allegations with, among other things: (i) the prior CEO's pre-Class Period admission that the

FDA protocol was complete; (ii) Riga's admission on May 3, 2018 that "[we are] in regular discussions with the FDA;" (iii) Turgeon's admission the same day that "we know what the requirements are" for BTD; (iv) Turgeon's post-disclosure admission that "the FDA's guidance on BTD" required "the efficacy of poziotinib in patients with mutations . . . to be compared to non-mutation specific non-small cell lung cancer patients," the best of which had a 22.9% ORR; and (v) the Company's ultimate disclosure that the "pre-specified" bar for FDA approval was 30% ORR. ¶¶88, 90-92, 169, 173, 177, 180. Even without these admissions, Turgeon and Riga's knowledge of this crucial information should be inferred, as it would be "absurd to suggest" that Spectrum executives in charge of promoting Pozi – one of the Company's two drugs – would not know the best competing treatment or the FDA requirements. *See S. Ferry*, 542 F.3d at 782, 785-86 (scienter inferred when "the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter").

Despite their inside knowledge, Turgeon and Riga repeatedly falsely told investors that existing treatments had only "6% to 8%" or "less than 10%" efficacy rates. ¶¶166-168, 171-172. Specifically, Turgeon made the following statements:

- **May 3, 2018**: "***Current therapies*** only have less than 10% – I think a ***6% to 10%*** response rate. So we have huge unmet need . . . ." ¶167.
- **May 16, 2018**: "[C]urrent TKIs ***and other therapies*** only have a ***6% to 8%*** response rate, huge unmet need." ¶168.

And Riga similarly said:

- **March 6, 2018**: "***Current therapies*** are unsatisfactory, and there is significant unmet need in this patient population. ¶166.
- **August 9, 2018**: "***[C]urrent available treatments is less than 10%***." ¶171.
- **November 8, 2018**: Pozi "***compares favorably*** to an overall response rate of ***less than 10%*** with available TKIs and a rate of ***less than 20%*** with the current standard of care second-line agents." ¶172.

Defendants do not dispute that they made these statements knowing the FDA would not approve Pozi unless it demonstrated a 30% ORR, much higher than the "6% to 8%" they repeatedly cited. ¶¶168-169, 173. Instead, they claim with "proper context" a "reasonable investor" "would

have understood" that "the 'less than 10%'" figure referred only to TKIs and "'neither stated nor implied anything regarding' FDA approval." Defendants' Motion to Dismiss the Second Amended Consolidated Class Action Complaint (ECF 99) ("MTD") at 6-9.[2] Defendants' argument is flawed in several important ways.

As an initial matter, the plain language of the statements directly conflicts with Defendants' proposed interpretation. *See Glazer Cap. Mgmt., LP v. Magistri*, 549 F.3d 736, 742 (9th Cir. 2008) (falsity adequately pled where "the plain language of the merger agreement" – that the company was "in compliance" with the Exchange Act – directly conflicted with reality); *In re STEC Inc. Sec. Litig.*, 2011 WL 2669217, at *7 (C.D. Cal. June 17, 2011) (falsity allegations sufficient "particularly" based on "the plain language of [the defendant's] statement"). Defendants claim Turgeon and Riga limited their statements "only to TKIs," but in reality they repeatedly claimed the low efficacy applied to "current therapies" and "current available treatments" generally. MTD at 9; ¶¶166-169, 171-173.[3] Defendants also argue they "'neither stated nor implied anything regarding' FDA approval," but that is exactly what they did. MTD at 6. For example, on August 9, 2018, Riga said "current available treatments is less than 10%" in direct response to a question from an analyst asking whether Spectrum had agreed with the FDA on a "response rate [and] PFS [Progression Free Survival] hurdle" for approval. ¶171.

Defendants suggest that the Court should ignore this plain language and instead look outside of the statements in order to understand "the context in which they were made." MTD at 6. But the "context" they identify bares no discernible relation to the statements themselves. Defendants point to a statement from Dr. John Heymach, who did not work at Spectrum, during a call ***five months before the Class Period*** on October 18, 2017. MTD at 6-7. Defendants claim investors knew to

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[2] Unless otherwise indicated, "Ex. _" references are to Defendants' exhibits attached to the Declaration of John B. Lawrence in Support of Defendants' MTD (ECF 100).

[3] In one instance, Turgeon attributed a 6%-8% ORR to "current TKIs and other therapies," which Defendants insist investors would understand as "'current . . . therapies' . . . ***in conjunction with*** other therapies." MTD at 9. Even if this strained interpretation could trump Plaintiff's well-pled allegations (it cannot), ***it is still false***. Chemotherapy alone returned an ORR of up to 19%. *See* the concurrently filed Declaration of Jeffrey J. Stein in Support of Lead Plaintiff's Opposition to Defendants' MTD ("Stein Decl."), Ex. 1 at 3.

connect the alleged statements to Dr. Heymach's disparate "context" because Turgeon and Riga sometimes used transitory phrases like "as a reminder" or "walk down memory lane" – and nothing more – before promoting the "6% to 8%" efficacy of "existing treatments." *Id.* at 7-9. This tenuous connection does not render Plaintiff's allegations implausible, particularly because proper context for statements generally comes from the surrounding statements in which they were made. *In re Iso Ray, Inc. Sec. Litig.*, 189 F. Supp. 3d 1057, 1067-68 (E.D. Wash. 2016) (declining defendants' invitation to look outside the press release at issue because "[s]tatements must be considered in the context of their total presentation").[4]

Finally, as a matter of common sense, Defendants' interpretation disregards investors' singular focus on the Company's financial success. Whether or not Pozi "solve[d] the steric hinderance [sic] limitations" of TKIs, investors wanted to know whether it could be approved by the FDA and turn a profit. MTD at 6; ¶166. In *Iso Ray*, defendants similarly argued that their statements "focuse[d] exclusively on [the treatment's] performance" and remained silent regarding its performance relative to other treatments. 189 F. Supp. 3d at 1069. The court rejected this characterization, writing "even if there was not a material misrepresentation, there was still a material omission" because the statement "precluded investors from judging for themselves just how much of an 'added benefit' there was . . . ***in comparison to the other treatment options***.'" *Id.* at 1070. Defendants' incomplete statements "'state the truth only so far as it goes, while omitting critical qualifying information'" about the actual FDA comparator. *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 258 (2024) (quoting *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 188 (2016)).

[4] Defendants' argument represents a "truth-on-the-market" defense, which is "intensely fact-specific" such that "courts rarely dismiss a complaint on this basis." *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1025 (C.D. Cal. 2008). Likewise, the Court cannot decide whether Defendants "disclosed" the 22.9% bar on October 18, 2017 when former CEO Shrotriya vaguely said "what I'm learning from [Dr. Heymach] is that these patients, the response to standard chemotherapy is 25% to 30%." Ex. 2 at 13. This distant statement uses the wrong ORR level and says ***nothing*** about the FDA using this higher bar for approval.

2. Defendants Misled Investors About the FDA Approval Target

Based on the "pre-specified" targets set by the FDA, Turgeon knew from the outset of the ZENITH20 trial in October 2017 that the FDA would not approve Pozi unless it returned a 30% ORR. ¶¶176-177. Despite this knowledge, on May 16, 2019, Turgeon falsely said: "I know as a drug developer, if I can get a 20% to 30% response rate, I can get a drug approved." ¶175.

Defendants attempt to minimize the impact of this objectively false statement, claiming it was nothing more than an "anecdote" in which Turgeon recalled ***what he used to think***. MTD at 10-11. But relaying stale, disproven information can materially mislead investors. *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 192 (2015) ("literal accuracy is not enough: An issuer must as well desist from misleading investors by saying one thing and holding back another."). And once Turgeon decided to make a statement about Pozi's bar for FDA approval – "anecdote" or not – he was "'bound to do so in a manner that wouldn't mislead investors.'" *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1009 (9th Cir. 2018).

Defendants' halfheartedly argue the statement is opinion, puffery or protected by the PSLRA's safe harbor. But Turgeon unambiguously spoke about his present knowledge concerning Pozi's approvability, even prefacing his comment with "I know." ¶175; *see, e.g.*, *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1144 (9th Cir. 2017) (statements go beyond "'feel good' optimistic statements" when they falsely describe the "past and present state of the [business]").[5]

3. Defendants Baselessly Expressed Optimism About BTD

From the outset of the MD Anderson trial in March 2017, Riga knew Pozi needed to demonstrate ***more than*** 43% ORR in the MD Anderson trial in order to secure BTD status. ¶180. As he admitted on May 3, 2018, Spectrum had "regular discussions with the FDA" about the MD Anderson trial protocol. *Id.* On August 9, 2018, he said: "[O]ur conversations with the agency,

[5] In a footnote, Defendants liken Turgeon's statement to an earlier statement he made that is not alleged to be false. MTD at 11 n.6. In the earlier statement, on May 3, 2018, he said "I thought" instead of "I know" and claimed the approval bar was "around 30%" instead of "20% to 30%." Ex. 4 at 10. These material differences only exemplify the misleading nature of Turgeon's allegedly false statement. In any event, Defendants are not excused for making misleading statements because they also made accurate ones. *See In re Vaxart, Inc. Sec. Litig.*, 576 F. Supp. 3d 663, 666-67 (N.D. Cal. 2021).

obviously, do go into the statistics that are expected, and we're very much aligned with the agency." *Id.* Then, on September 24, 2018, Spectrum publicly announced the final MD Anderson trial results, in which Pozi demonstrated an efficacy of 43% ORR. *Id.* Riga knew – but investors did not – that this result did not meet the level pre-specified by the FDA.

On November 8, 2018, after Riga learned the failed results but before he announced them publicly, he misleadingly reported that Pozi "is showing indications of being substantially better than currently available treatments" and, accordingly, he "believe[s] the drug qualifies" for BTD. ¶178.[6] Riga's purported "belief" is actionable because he had no basis for it, and failed to disclose inside information demonstrating failure. *Omnicare*, 575 U.S. at 185-86; *Todd v. STAAR Surgical Co.*, 2016 WL 6699284, at *9 (C.D. Cal. Apr. 12, 2016) ("Simply inserting the word 'believe' in front of a statement of fact does not, therefore, immunize Defendants from liability.").[7]

Defendants again spend their argument urging the Court to consider the "context" surrounding Riga's statements. MTD at 11. They claim that, even though Turgeon said "[w]e know what the requirements are" for BTD, investors understood he did not mean the specific target for Pozi, but only the general requirement that a drug must demonstrate a "substantial improvement over existing therapies." *Id.* But it makes no sense that Riga would need private conversations with the FDA to learn the generally understood BTD standard. In any event, Riga himself eviscerated Defendants' proposed interpretation on August 9, 2018, when he said: "[O]ur conversations with the agency, obviously, do go into the statistics that are expected." ¶180.

4. Plaintiff Pled a Strong Inference of Scienter in the MD Anderson Trial

The SAC provides detailed scienter allegations including real-time admissions from Defendants that the FDA was "in regular discussion" with Turgeon and Riga about protocols,

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[6] Riga's phrasing mirrors the FDA's "substantial improvement" requirement for BTD. ¶59.

[7] This statement is also not protected by the PSLRA's safe harbor, as Riga failed to disclose known information undermining his statement. *HsingChing Hsu v. Puma Biotechnology, Inc.*, 2017 WL 3205774, at *3 (C.D. Cal. July 25, 2017) ("Defendants shouldn't benefit from safe harbor by simply saying they 'anticipated' success when, in fact, they had a reasonable belief that defeat was just around the corner.").

including the "requirements" and "statistics" needed to obtain BTD status and FDA approval. ¶¶170, 174, 180. "It is unclear what further facts plaintiffs would need to plead to create a stronger inference that [they] had access to information [they] discussed publicly." *Reese v. Malone*, 747 F.3d 557, 572 (9th Cir. 2014); *OSI*, 2015 WL 1985562, at *12 ("scienter can be established by the fact that the Defendants touched on the specific issue . . . in their public statements"); *Washtenaw Cnty. Emps. Ret. Sys. v. Celera Corp.*, 2012 WL 3835078, at *3 (N.D. Cal. Sept. 4, 2012) ("[t]he wording of [d]efendants' statements . . . suggests they understood what was going on"); *Loritz v. Exide Techs.*, 2014 WL 4058752, at *12 (C.D. Cal. Aug. 7, 2014) (same). Here, it is just common sense that Defendants would know the hurdles Spectrum needed to clear in its clinical trials.

Defendants do little to confront Plaintiff's scienter allegations. Instead, they claim Plaintiff's "irrational theory" "'does not make a whole lot of sense'" because executives would not provide false information knowing the falsity would ultimately be revealed. MTD at 11, 13. But, as Plaintiff explained, Spectrum was a small company that could not afford bad news, and therefore concealed it. ¶¶2-3. *Makor Issues & Rts., Ltd. v. Tellabs Inc.*, 513 F.3d 702, 710 (7th Cir. 2008) ("[t]he fact that a gamble – concealing bad news in the hope that it will be overtaken by good news – fails is not inconsistent with its having been a considered, though because of the risk a reckless, gamble"). Even if this fraudulent strategy seems ill-advised in retrospect (as they often do), "the securities laws forbid foolish frauds along with clever ones." *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 728 (7th Cir. 2004) (Easterbrook, J.). In any event, "[t]he absence of a motive allegation, though relevant, is not dispositive." *Siracusano*, 563 U.S. at 48.[8]

B. Plaintiff Pled Misstatements During the Pozi ZENITH20 Trial

1. Defendants Misled Investors About the Viability of Pozi

From the outset of the ZENITH20 trial in October 2017, Defendants knew Pozi needed to demonstrate an ORR of at least 30% to support FDA approval. ¶¶184, 187, 190. On August 9, 2018, Turgeon said "[w]e have alignment with the agency on our Phase II clinical trial," and Riga

[8] Defendants suggest that falsity must be "patently obvious" to support scienter, but that is not the law. MTD at 13. Defendants' case, *Westley v. Oclaro, Inc.*, 897 F. Supp. 2d 902, 934 (N.D. Cal. 2012), holds only that "scienter ***may*** readily be inferred where there is obvious falsity."

made clear that "our conversations with the agency, obviously, do go into the statistics that are expected." ¶¶184, 187, 190. On September 11, 2019, Turgeon clarified that during Spectrum's conversations with the FDA, they "got the approval on the ends" – or endpoints – of the ZENITH20 trial. *Id.* On October 2, 2019, Turgeon made clear that "[w]e have all pre-specified endpoints . . . [s]o, we feel we know how high we have to jump." ¶91. Ultimately, Spectrum revealed the "pre-specified" endpoint for Cohort 1 was 30% ORR, and the "pre-specified" endpoint for Cohort 3 was "a little higher" than 30% ORR. ¶¶184, 187, 190, 208-209, 211.

Defendants also knew how Pozi was performing during the ZENITH20 trials. Defendants had access to the trial data because it was "open label," which Lebel conceded meant they "could've looked at the data." ¶98. According to corroborating accounts from CW-1, who worked at a clinical site, and CW-2, who worked at Spectrum and oversaw the clinical sites, Spectrum controlled a database throughout the trial that housed real-time data, including safety statistics and final conclusions for each patient about the effectiveness of Pozi. ¶¶22-27, 36-38.[9] CW-1 uploaded all the data he/she collected to a database controlled by Spectrum and received calls from "a whole bunch" of Spectrum employees to discuss the results. ¶27. CW-2 attended meetings during the clinical trial where Lebel expressed disappointment in the undisclosed safety data, demonstrating that he had personally accessed the database. ¶41. *See In re Countrywide Fin. Corp. Derivative Litig.*, 554 F. Supp. 2d 1044, 1058 (C.D. Cal. 2008) ("Corroboration from multiple sources also supports an inference of scienter."). Turgeon and Riga also referenced their access to and inspection of the data during the ZENITH20 trial. ¶¶184, 187, 190 (Riga, on May 3, 2018: "we believe that pozi meets the criteria ***if the early data continues***"); *id.* (Turgeon, May 16, 2018: "I got an update yesterday on the enrollment" of the ZENITH20 trial).

Data from the trial was readily available to Defendants within 67 days of initiation of treatment: 56 days to complete the course of medication and 11 days for doctors to analyze results and upload conclusions to the database. ¶111. Accordingly, since Cohort 1 was fully enrolled on

[9] ORR is a simple percentage of the total patients for whom the drug was effective. ¶74.

January 2, 2019 and Cohort 3 was fully enrolled on April 28, 2020, Defendants had access to fully confirmed data by March 10, 2019 and July 4, 2020, respectively. ¶¶111-112.

The data from Cohorts 1 and 3 revealed that Pozi was an ineffective and intolerable medication. Cohort 1 returned an efficacy of just 14.8% – far worse than existing therapies – with ***88%*** of patients needing dose interruptions and ***68%*** needing dose reductions due to significant AEs. ¶¶199, 203. In Cohort 3, the data confirmed that Pozi could not clear the >30% ORR threshold, returning a failing ORR of 27.8%. ¶¶207, 210, 213-214, 218. And the safety data got even worse, with 94% of patients undergoing dose interruptions. ¶¶213, 218. Both CW-1 and CW-2 confirmed that side effects directly impacted the ZENITH20 efficacy results, as many patients had to drop out of the trial because the AEs were so severe. ¶¶218-219. Rather than disclose the known bad data to investors, Defendants hid the results and made materially misleading statements. They expressed optimism for Pozi's future, highlighted the outdated results, and minimized Pozi's significant AEs.

Defendants Baselessly Expressed Optimism for Pozi Without Disclosing Known Negative Results. Riga, Turgeon, and Lebel each made misstatements expressing optimism for Cohort 1 results after receipt of data showing it failed. "[E]ven 'general statements of optimism, when taken in context, may form a basis for a securities fraud claim' when those statements address specific aspects of a company's operation that the speaker knows to be performing poorly." *Quality*, 865 F.3d at 1143. On August 8, 2019, after holding the data for five months, Riga said: "[W]e feel really strong about . . . the data readout in Q4." ¶188. On October 2, 2019, after holding the data for seven months, Turgeon told investors that Pozi was ahead of competitors, saying "it's nice to be in pole position and we certainly are that['s] why because we have two fully enrolled trials and – where others are just getting started." ¶182. On the same day, Lebel suggested that modifications to the Cohort 1 protocol "should play in our favor" and could lead to better results than the MD Anderson trial. ¶185. Investors bought in to Defendants' story. On November 10, 2019, a Jefferies analyst echoed Defendants' assurances, writing that ZENITH20 protocols "could boost ORR some," and return a better result than the MD Anderson trial. ¶123.

Likewise, after receipt of disappointing data for Cohort 3, Turgeon and Lebel continued to misrepresent the future of the drug. On November 4, 2020, four months after receipt of the bad data,

Turgeon said: "I'm really confident in our ability to meet our corporate objectives and advance our programs with the aspiration of bringing new treatments to the patients with cancer who need it." ¶206. And on July 7, 2020, Lebel suggested "cohort 3 could behave differently" than failed Cohort 1. ¶209. Analysts again parroted Defendants' misrepresentations. On August 11, 2020, a Jefferies analyst said Cohort 3 could "potentially mitigat[e] tox/AEs presumed to have led to dose reductions/interruptions and poorer efficacy in Cohort 1." ¶130.

Defendants Touted Outdated Results. Turgeon, Riga, and the Company reported outdated MD Anderson trial results without disclosing newer and more reliable Cohort 1 results in their possession. The Ninth Circuit is clear that defendants cannot tout positive old data when they "allegedly knew already that the 'new data' revealed" a negative outcome. *Khoja*, 899 F.3d at 1016; *see also City of Birmingham Relief & Ret. Sys. v. Acadia Pharms., Inc.*, 2022 WL 4491093, at *10 (S.D. Cal. Sept. 27, 2022) (failure to disclose "disappointing subgroup data rendered [d]efendants' positive statements regarding the results of the studies materially misleading").

On September 11, 2019, despite possession of the failed Cohort 1 data for six months, Turgeon referred investors to the "43% overall response rate" from the MD Anderson trial, which he said was "much higher than anything." ¶191. Likewise, on October 2, 2019, Lebel said Pozi "has shown a response rate of 43% or so." ¶194. And in its SEC Form 10-Q filed on May 9, 2019 and signed by Turgeon and Gustafson, Spectrum reported "the confirmed overall response rate was 43%." ¶197. After receiving the Cohort 3 data, in a prospectus supplement filed July 30, 2020, Spectrum reported "the confirmed overall response rate was 43%," without disclosing known results from Cohort 3. ¶212.[10]

Defendants Misrepresented the Severity of Adverse Events. Lebel made false and misleading statements about Pozi's Cohort 1 performance from a safety perspective, failing to disclose significant AEs that undercut the approvability of the drug. *See Amgen*, 544 F. Supp. 2d at 1030 ("[d]efendants created the false impression that the DAHANCA 10 Trial was proceeding

[10] Defendants point out that they did disclose Cohort 1 results in this filing, which is hardly exculpatory since those results had already been disclosed publicly. MTD at 13 n.13. Defendants do not dispute that they withheld the as-yet-undisclosed Cohort 3 results.

smoothly when in fact it had been halted due to safety concerns"). On October 2, 2019, seven months after receiving negative Cohort 1 data, Lebel said modifications to AE protocols "should play in our favor." ¶201. And on March 10, 2020, after Spectrum announced the failed Pozi trial, but before disclosing AEs as a contributing factor, Lebel incorrectly reported that "2/3 of the patients had some form of dose interruption," when the real number was ***88%***. ¶¶202-203.

Lebel also failed to disclose Pozi's poor Cohort 3 safety performance. On May 7, 2020, he said Cohort 3 patients should be "more tolerant of adverse events" than Cohort 1 patients, despite knowing that patients in Cohort 3 experienced dose reductions at a higher percentage (88% vs. 94%). ¶¶215, 218. On the same call, Lebel said: "we believe . . . we could mitigate the amount of adverse events we see" in Cohort 3. ¶216. And on November 4, 2020, he admitted Spectrum "monitor[s] these cohorts . . . for signals that would be out of the ordinary," and assured investors that "we have not had to make any announcement" regarding unusual findings. ¶217.

2. Defendants' Falsity Arguments Lack Merit

In response to the ZENITH20 statements, Defendants argue that Plaintiff "pleads no facts" and provides "no particularized allegations" supporting the ZENITH20 claims. MTD at 14, 17. But Defendants conflate Plaintiff's obligation to plead ***particularized*** facts with an obligation to provide ***uncontroverted*** facts that Defendants concede. Rather than point to an ***absence*** of allegations, Defendants spend their pages simply disagreeing with the detailed allegations included in the SAC. But "[i]n considering a motion to dismiss under Rule 12(b)(6), the court must accept as true all material allegations in the complaint as well as all reasonable inferences that may be drawn from such allegations." *Takiguchi v. MRI Int'l, Inc.*, 47 F. Supp. 3d 1100, 1108 (D. Nev. 2014) (citing *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1150 n.2 (9th Cir. 2000)). Here, Plaintiff's allegations easily create a reasonable inference of falsity.

a. Plaintiff Pled Access to Data

Defendants attempt to dispute Plaintiff's well-pled allegations about Defendants' access to data in several ways, none of which is successful. ***First***, Defendants argue that Plaintiff "pleads no facts" suggesting that they had access to data because the trial was "'open label.'" MTD at 14. But, in arriving at the conclusion, Defendants completely disregard the alleged ***fact*** that Lebel repeatedly

admitted that "open label" meant they had access. On October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory . . . we could've look at the data." ¶221. On May 7, 2020, he said ZENITH20 was "an open trial" such that "there will be regular looking at the data." ¶223. And on August 10, 2020, he said: "Obviously we're looking at the data. It's an open-label study." *Id.* Defendants also overlook the alleged ***fact*** that both CW-1 and CW-2 ***confirmed*** Spectrum had access to and received "everything we collected in the regular course of business," including final conclusions about the drug's efficacy and safety. ¶¶26, 38, 223.

Second, Defendants complain Plaintiff "pleads no facts" to support the allegation that Defendants had access to trial data within 67 days after final enrollment in Cohorts 1 and 3. MTD at 14. But Plaintiff supports that allegation with the alleged ***facts*** that: (i) Pozi's course of treatment lasted 56 days; and (2) CW-1, who worked for a participating clinic, said it took an additional 11 days for those results to be uploaded to Spectrum's database. ¶¶25, 27, 111. This timeline is reasonable and factually supported; nothing more is required. *Sec. & Exch. Comm'n v. Humphries*, 2022 WL 17668022, at *7 (D. Nev. Dec. 13, 2022) (Silva, J.) (allegations pled with particularity where the complaint described "the approximate time period that [the defendant] was involved in the scheme and detail[ed] his actions in furtherance of the scheme"). In any event, Defendants' ostensibly only challenge the timeline on the fringes, suggesting it should be slightly longer because other clinics may have worked slower than CW-1's clinic, or patients may have started treatment ***after*** they enrolled in the study, or senior executives may not have accessed the database immediately. MTD at 14-15. But the alleged statements occurred ***months*** after Defendants received the data, so a slightly longer timeline does nothing to excuse their misrepresentations.[11]

Third, Defendants offer competing interpretations of their statements admitting access to data. For example, Defendants claim Riga's statements that "we've, obviously, looked at that data in detail" and "we feel really strong about . . . the data readout in Q4" (¶188), were referring to "'a

[11] Defendants' citation to *Dresner v. Silverback Therapeutics, Inc.*, 2023 WL 2913755 (W.D. Wash. Apr. 12, 2023) does not suggest otherwise. There, the court acknowledged, "a company could have access to data at all times," but "[p]laintiffs would need factual allegations other than an 'open label' status to demonstrate this" – which is precisely what Plaintiff has provided here. *Id.* at *10.

competitor's study for a different drug.'" MTD at 16. But Pozi – not the competing drug – had a readout upcoming in Q4. And while Defendants claim the analyst posing the question asked only about competition, that is simply incorrect. *Id.* In reality, he asked for Riga's "thoughts on [the competitor's] data ***versus*** the pozi data." ¶188. The reasonable inference is that Riga was referring to Pozi data: Riga telling investors he felt strongly about competing data is illogical.

Likewise, Defendants offer a different interpretation for Lebel's admission that ZENITH20 was "an open trial" such that "there will be regular looking at the data." ¶223. They claim he meant they would review the data much later, "once we get [results] back from our central imagining lab," but fail to reconcile his admission that Defendants' review would occur "'before we fully enroll.'" *Id.*; MTD at 16. Defendants also argue the Court should disregard their statements admitting access to data because elsewhere in conference calls they denied having access until after review of an Independent Data Review Committee. MTD at 15. But these denials ***are alleged to be false in the SAC***. ¶¶220-223. Defendants' own denials of fraud are not exculpatory. *Williamson v. United States*, 512 U.S. 594, 599-600 (1994) ("[s]elf-exculpatory statements are exactly the ones which people are most likely to make even when they are false"). And CW-1, who collected ZENITH20 data, said "he/she was never made aware that there was an Independent Data Review Committee," and instead "always spoke directly to Spectrum personnel" when relaying trial results. ¶30. Defendants' attempts to muddy the waters with varying interpretations are inappropriate at the pleading stage. *See Gilead*, 536 F.3d at 1057; *see also Zachary Salzman v. ImmunityBio, Inc.*, 2024 WL 3100274, at *7 (S.D. Cal. June 20, 2024) (declining defendants' argument that "require[d] the Court to ignore the plain meaning of [their statements]").

Fourth, Defendants attempt to undermine the inside information provided by CW-1 and CW-2, saying they do not establish "whether Defendants ever received that information." MTD at 16.[12] But CW-2 recounted how Lebel personally referenced the poor performance of the drug at

[12] In their scienter analysis, Defendants likewise suggest that Plaintiff must establish that Defendants "***actually*** received or reviewed that data." MTD at 23. But at the hearing for their previous motion, Defendants instead asked "was this data even at the company?" *See* ECF 92 at 15:20. They have moved the goalpost in light of Plaintiff's bolstered allegations in the SAC, which includes CW accounts establishing that Spectrum had the data in real time and regularly reviewed it. None of Defendants' cited cases require more. MTD at 16, 23-24. For example, in *Gammel v.*

meetings, and Turgeon and Riga both referenced the data before it was publicly available. *See, e.g.*, ¶187. CW-1 and CW-2 explained that clinical trial sites uploaded data and conclusions for Spectrum to review throughout the clinical trials. ¶¶24, 27, 37-38.[13] Lebel himself acknowledged: "***Obviously***, we're looking at data. It's an open-label study." ¶¶98. "'[T]he most direct way to show both that a statement [is] false when made and that the party making the statement knew it was false is via contemporaneous reports or data, available to the party, which contradict the statement.'" *Hsu v. Puma Biotech., Inc.*, 213 F. Supp. 3d 1275, 1287 (C.D. Cal. 2016). In any event, direct access is not required. *See In re Alphabet, Inc. Sec. Litig.*, 1 F.4th 687, 706 (9th Cir. 2021) (upholding allegations based on access to memo even though "the complaint does not directly allege that [defendant] read the [memo]" because the information was "highly material to Google's operations").

Defendants also repeatedly mischaracterize accounts from CW-1 and CW-2. For example, they claim Defendants received only "raw data" from clinical sites, even though CW-1 explained the clinics provided specific information concerning "adverse events" and "final determination[s] of a patient's response to the drug." ¶¶26-28. CW-2 confirmed that the database included "efficacy graphs and safety printouts." ¶38.[14] Defendants also claim "CW-2 does ***not*** suggest Lebel received any information contradicting his public statements," even though CW-2 reported that Lebel knew "the Pozi dose was too high" before the Company disclosed the concerning safety data. MTD at 17;

Hewlett-Packard Co., 905 F. Supp. 2d 1052, 1079 (C.D. Cal. 2012), the court discounted a CW's account only because she merely "imagine[d]" defendants' access and elsewhere suggested they "did not know" the relevant information. And in *Brodsky v. Yahoo! Inc.*, 630 F. Supp. 2d 1104, 1117-18 (N.D. Cal. 2009), the court found defendants' access to information irrelevant because, unlike here, they "never publicly denied" that access.

[13] The CW accounts support an inference of scienter against Turgeon and Riga, even though they did not contact them directly. The Ninth Circuit routinely credits CWs even when the CWs do not interact with a defendant. *See, e.g.*, *Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 772 (9th Cir. 2023) (crediting accounts of low-level CWs who had no direct contact with defendants); *Quality*, 865 F.3d at 1145 (same).

[14] These details readily establish Defendants' scienter as well. In their scienter argument, Defendants claim Plaintiff failed to provide "any description of how this information supposedly revealed Cohorts 1 and 3 had (or even would) miss the alleged primary endpoint" and then cite a purported "wall of authority" in support of their position. MTD at 24. But the cases they cite criticize Plaintiff's allegations only when they "'do[] not plead ***any*** details'" or "'do not allege the content'" of the data. *Id.* at 24 n.29. Here, by contrast, Plaintiff describes the data in detail.

¶41. Finally, they discredit CW-1's knowledge because he/she stopped working for the clinical trial site "before the first alleged misrepresentation about ZENITH20," but ***that is when the ZENTIH20 trial occurred***. MTD at 16. Pre-class period confidential witness accounts contribute to a finding of scienter when they are "relevant and probative." *See E. Ohman J:or Fonder AB v. NVIDIA Corp.*, 81 F.4th 918, 939 (9th Cir. 2023).

b. Plaintiff Pled Material Adverse Events

Defendants next argue that Plaintiff provided "no particularized allegations" suggesting Pozi's AE profile warranted disclosure. MTD at 17-18. They argue the AEs in Cohorts 1 and 3 did not impede FDA approval because "Cohort 2 reported AEs akin to Cohorts 1 and 3, yet the FDA permitted Spectrum to file an NDA based on that data and even granted Pozi fast-track designation." MTD at 18. But Defendants leave out the rest of the story. As outlined in the SAC, the FDA ultimately denied approval of Pozi after "repeatedly express[ing] concern to Spectrum regarding Pozi's adverse event profile" in Cohort 2. ¶163. Defendants' misrepresentations concerning AEs in Cohort 2 led to a separate securities fraud class action complaint, which the Southern District of New York sustained in January 2024. *See Christiansen v. Spectrum Pharms., Inc.*, 2024 WL 246020, at *1 (S.D.N.Y. Jan. 23, 2024); *see also* ¶163.

Defendants also dispute whether the AEs impacted Pozi's efficacy results, claiming accounts from CW-1 and CW-2 are "speculation and hearsay." MTD at 18. But CW-1 and CW-2 participated in and oversaw the ZENITH20 trial, respectively, so their accounts are first-hand and reliable. Even so, at the pleading stage hearsay from CWs is "sufficiently plausible and coherent to support" allegations. *In re Cadence Design Sys., Inc. Sec. Litig.*, 692 F. Supp. 2d 1181, 1189 (N.D. Cal. 2010); *see also Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1208-09 (9th Cir. 2016) (reversing dismissal where witness account was improperly dismissed as hearsay).

c. Plaintiff Pled Multi-Centered Trials Perform Worse

Finally, Defendants dispute Plaintiff's "implausib[le]" allegation that ZENITH20, as a multi-center trial, would perform worse than the MD Anderson trial, a single-study trial at a world class clinic. MTD at 19. But Lebel ***admitted*** "[w]henever you have a single site study in general the data often is a little bit better than when you do a multi-center study." ¶185.

d. The Alleged Statements Are Not Puffery

Defendants challenge only four statements as puffery. MTD at 20 (citing ¶¶182, 188, 206, 216). Even seemingly innocuous statements may still "be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation." *Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989); *see also Quality*, 865 F.3d at 1143. Here, Defendants induced reliance when they repeatedly expressed optimism about Pozi without disclosing known, non-public information that Pozi failed to hit FDA targets.

e. The Alleged Statements Are Not Protected by the PSLRA's Safe Harbor

Defendants identify eight optimistic statements as forward looking, because they discuss upcoming results. MTD at 20-21 (citing ¶¶185, 188, 201, 206, 209, 215-217). But corporations cannot "benefit from safe harbor by simply saying they 'anticipated' success when, in fact, they had a reasonable belief that defeat was just around the corner." *HsingChing.*, 2017 WL 3205774, at *3. Additionally, statements concerning the present knowledge of the speaker are not forward-looking under the PSLRA. *See City of Miami Gen. Emps' & Sanitation Emps' Ret. Tr. v. RH, Inc.*, 302 F. Supp. 3d 1028, 1040 n.6 (N.D. Cal. 2018) ("present-tense" statements actionable); *In re Atossa Genetics Inc. Sec. Litig.*, 868 F.3d 784, 801 (9th Cir. 2017) (defendant's "emphasis on the past tense indicates that [he] was referring to prior events," and therefore the statements were not forward-looking); *Quality*, 865 F.3d at 1142 ("where defendants make mixed statements containing non-forward-looking statements as well as forward-looking statements, the non-forward-looking statements are not protected by the safe harbor of the PSLRA"). Five of the statements Defendants identify are in the present tense:

- "We ***understand*** and we ***believe*** on the basis of the data and modeling ***we've done*** . . . ." ¶216.
- "[T]he data readout in Q4 . . . ***is well ahead***." ¶188.
- "***[W]e monitor*** safety on all our studies." ¶217.
- "[A]dditionally, what we've done is ***we prophylax*** every patient for – against diarrhea." ¶201.

- "***I'm really confident*** in our ability to meet our corporate objectives." ¶206.

Even if Defendants made purely forward-looking statements, the PSLRA's safe harbor protects only "certain" forward-looking statements – those not "made 'with actual knowledge . . . that the statement was false or misleading'" or "'accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.'" *Quality*, 865 F.3d at 1141 (alteration in original). Defendants do not pass either of these hurdles.

Defendants claim six misstatements were accompanied by cautionary language. MTD at 21-22 (citing ¶¶188, 206, 209, 215-217). But "language is not 'meaningful' [when] it amounts to only a boilerplate listing of generic risks and does not mention the specific risk." *Glazer*, 63 F.4th at 780. The language "must be 'precise,' and 'directly address[]'" the misrepresentation such that "'the risk of real deception drops to nil.'" *In re BioMarin Pharm. Inc. Sec. Litig.*, 2022 WL 597037, at *3 (N.D. Cal. Feb. 28, 2022). Cautionary language is not adequate when it warns of risks that have already materialized. *See Khoja*, 899 F.3d at 1016 (a warning that study results "'***may***'" be inconsistent with interim study results was misleading because the company "allegedly knew already that the 'new data' revealed exactly that") (emphasis in original); *Weston v. DocuSign, Inc.*, 2023 WL 3000583, at *17 (N.D. Cal. Apr. 18, 2023) (disclosures that pandemic """could""" impact business was misleading where "those risks may have already come to fruition"). Defendants cite only inadequate form language that failed to inform investors about critical known data and results demonstrating that Pozi was intolerable and ineffective.[15]

As described *supra* §2(a) and *infra* §3, the SAC sufficiently alleges that the Individual Defendants had actual knowledge that their statements regarding Pozi were false and misleading

[15] Defendants claim they "couched" some of their statements with tempering language like "'it [is] very hard to predict'" and "'potentially.'" MTD at 21-22. But Defendants cannot escape liability by feigning ignorance. *SEC v. Platforms Wireless Int'l Corp.*, 617 F.3d 1072 (9th Cir. 2010) ("[w]hen the defendant is aware of the facts that made the statement misleading, 'he cannot ignore the facts and plead ignorance of the risk'") (quoting *Tellabs*, 513 F.3d at 704). In any event, "the mere inclusion of some cautionary language is not enough to determine as a matter of law that statements were not misleading." *In re Stratosphere Corp. Sec. Litig.*, 1 F. Supp. 2d 1096, 1117 (D. Nev. 1998).

when made. *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001) ("falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts"); *In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d 714, 741 (N.D. Cal. 2022).

f. The Alleged Statements Are Not Inactionable Opinions

Defendants challenge 12 statements as inactionable opinions. MTD at 23 (citing ¶¶182, 185, 188, 191, 194, 201-202, 206, 209, 215-217). Opinions are actionable when: (1) the speaker does not "actually hold[] the stated belief"; (2) the opinion contains a materially false "embedded statement[] of fact"; or (3) omitted information shows that the speaker "lacked the basis for making those statements that a reasonable investor would expect." *Omnicare*, 575 U.S. at 184-85, 196. Statements must "fairly align[] with the information in the issuer's possession at the time" they were made. *Id.* at 189. Defendants claim they merely provided their "subjective" positive view on Pozi's status and prospects. MTD at 23. But they cannot escape liability because they failed to qualify their statements with known information about the failed ZENITH20 trials that completely undermined their stated opinions.

3. Plaintiff Pled a Strong Inference of Scienter in the ZENITH20 Trial

In addition to direct allegations demonstrating that Defendants accessed information undermining their statements, Plaintiff has provided a host of other indicia of Defendants' scienter, including, *inter alia*, their close proximity to the information, their highly suspicious stock sales, concurrent Company financings, executive departures, and Sarbanes-Oxley ("SOX") certifications.

a. Defendants Knew the Status of Spectrum's Core Drug

Courts impute scienter to Defendants "based on the inference that [they] have knowledge of the 'core operations' of the company." *Reese*, 747 F.3d at 575; *see also S. Ferry*, 542 F.3d at 782. When "the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter," scienter may be inferred on the basis of the core operations doctrine alone. *S. Ferry*, 542 F.3d at 786. Courts also "consider a senior executive's role in a company to determine whether there is a cogent and compelling inference that the senior executive knew of the information at issue." *Alphabet*, 1 F.4th at 706; *In re Splunk Inc. Sec. Litig.*,

592 F. Supp. 3d 919, 944 (N.D. Cal. 2022) (scienter alleged where Defendants were aware of the adverse facts "by virtue of their executive roles and because of the importance of the adverse facts to the company[]").

Here, Pozi represented one of only two products the Company owned. Defendants led the effort to get Pozi approved, interacted directly with the FDA about the requirements for approval, and regularly commented on the status of the ZENITH20 trial and the drug's efficacy and safety profiles during conference calls with investors. On November 7, 2019, Turgeon said: "Our focus is crystal clear. We're developing 2 late-stage assets [Pozi and Rolontis] and expanding the pipeline." ¶272. It would be "absurd" to imagine that senior management remained unaware of critical information on a Company-controlled database. *Salzman*, 2024 WL 3100274, at *11 (finding scienter where company "'did not generate any meaningful revenues from the commercial sale of any other products'").

b. Defendants Traded Stock at Suspicious Times[16]

"'Unusual trading or trading at suspicious times or in suspicious amounts by corporate insiders has long been recognized as probative of scienter.'" *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022 (9th Cir. 2005). "To evaluate suspiciousness of stock sales, [the Ninth Circuit] consider[s], *inter alia*, three factors: (1) the amount and percentage of shares sold; (2) timing of the sales; and (3) consistency with prior trading history." *Nursing Home Pension Fund, Loc. 144 v. Oracle Corp.*, 380 F.3d 1226, 1232 (9th Cir. 2004).

The timing of sales is suspicious when they appear calculated "'to maximize the personal benefit from undisclosed inside information.'" *Am. W.*, 320 F.3d at 940. In both Cohort 1 and Cohort 3, Defendants had fully confirmed data months before investors learned about the failed

[16] Although Defendants acknowledge that the Court must conduct a "holistic review" of Plaintiff's scienter allegations for the statements made during the ZENITH20 trial, they do not discuss Defendants' stock sales, the ATM financing, the executive departures, or the SOX certifications in that section. MTD at 26. To be clear, all those scienter allegations should be included in the holistic analysis. "Even if no single allegation, standing alone, is 'sufficient to give rise to a strong inference of scienter,' a holistic review of all the allegations may 'combine to give rise to a strong inference of scienter.'" *NVIDIA*, 81 F.4th at 940 (quoting *Glazer*, 63 F.4th at 766).

result.[17] Defendants capitalized on these periods of information imbalance by lining their own pockets. On March 25, 2019, just two weeks after receiving the negative data, Gustafson initiated a series of five stock sales, in total his second largest sale ever. ¶259. On May 16, 2019, Turgeon initiated sales comprising 9% of his holdings. *Id.* Then, on November 18, 2020, with Cohort 3 data in hand, Turgeon sold 24% of his holdings. ¶261. On December 16, 2020, just six days before the disclosure of the failed Cohort 3, Turgeon sold 29% of his remaining shares. *Id.* In Turgeon's two transactions in the weeks leading up to the announcement of Cohort 3's failure, ***he dumped 44% of his shares***, completely undermining his simultaneous public assertions of "confidence" in the Company. *Id.* Gustafson also sold shares during this time period, unloading 7% of his shares on December 14, 2020. *Id.* Meanwhile, Defendants repeatedly assured investors that the results could be positive. If Defendants really believed the Pozi results were going to be positive, then they would have held their shares until after the results were announced.[18]

Defendants claim three of the alleged stock sales are not suspicious because Defendants unloaded "under 8%" of their shares. MTD at 34. But courts in this Circuit have found similar amounts of insider sales suspicious. *See, e.g.*, *Batwin v. Occam Networks, Inc.*, 2008 WL 2676364, at *14-*15 (C.D. Cal. July 1, 2008) (7%); *In re SeeBeyond Techs. Corp. Sec. Litig.*, 266 F. Supp. 2d 1150, 1169 (C.D. Cal. 2003) (7.6%); *Oracle*, 380 F.3d at 1232 (2.1%).

With respect to prior trading history, Defendants claim Turgeon's and Gustafson's Class Period sales were not suspicious because they "disposed of" shares for "tax-withholding purposes" prior to the Class Period. MTD at 33. But these pre-Class-Period ***withholdings*** contrast sharply with Turgeon's and Gustafson's much larger and suspiciously timed ***sales*** during the Class Period. In any event, courts find stock sales support scienter even without "any trading history." *See, e.g.*, *Karinski v. Stamps.com, Inc.*, 2020 WL 281716, at *15 (C.D. Cal. Jan. 17, 2020); *see also Acadia*, 2022 WL 4491093, at *13 (sales probative of scienter solely because "the amount of . . . stock sold

[17] Cohort 1 results were available on March 10, 2019, but not disclosed until December 26, 2019. Cohort 3 results were available July 4, 2020, but not disclosed until December 22, 2020. ¶¶95-96.

[18] Defendants wrongly assert that Plaintiff contests all 87 sales the Individual Defendants made during the Class Period but the SAC only challenges 19 sales. MTD at 33-34; *see also* ¶¶259-263.

by the individual [d]efendants . . . is substantial"); *In re Questcor Sec. Litig.*, 2013 WL 5486762, at *16-*17 (C.D. Cal. Oct. 1, 2013) (trades probative of scienter where only two factors met); *Baron v. Hyrecar Inc.*, 2022 WL 17413562, at *15 (C.D. Cal. Dec. 5, 2022) (same).[19]

Defendants also claim their Class Period sales were not suspicious because they made them without discretion either "to meet tax obligations" or pursuant to "predetermined conditions" in a "10b5-1 plan." MTD at 34. To support this assertion, they cite to a footnote ***they authored*** in their Form 4 filings, which claims "[t]his transaction was effected pursuant to a Rule 10b5-1 trading plan adopted by the reporting person for the purpose of satisfying tax withholding obligations." Ex. 33. The Court should disregard this argument for several reasons. ***First***, Defendants cannot present their own version of the facts at the pleading stage. *Immanuel Lake v. Zogenix, Inc.*, 2020 WL 3820424, at *4 (N.D. Cal. Jan. 27, 2020). ***Second***, the Forms 4 themselves contradict the footnote. Pursuant to the SEC's instructions regarding the completion of Forms 4, insiders must indicate whether the disclosed transaction is a sale or a withholding of shares for tax purposes, by putting either an "S" for sale or an "F" for withholding in box 3. *See* Stein Decl., Ex. 2 at 7. The alleged sales – which Defendants claim are actually withholdings – are clearly designated as sales. *Id.* ***Third***, the Forms 4 filed before the Class Period make no mention of a 10b5-1 plan, suggesting the plan(s) went into effect during the Class Period. *See Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 201 (S.D.N.Y. 2010) ("Trading plans are not a cognizable defense to scienter allegations on a motion to dismiss where, as here, they were adopted during the [c]lass [p]eriod."). ***Fourth***, "'the existence of a Rule 10b5-1 Trading Plan is an affirmative defense that must be pled and proved'" and is not appropriate for a motion to dismiss. *Id.* at 200-01. ***Fifth***, the trades themselves demonstrate they were not "automatic." MTD at 34. For example, Defendants do not – and cannot – explain why a preset 10b5-1 or tax plan would require the CEO to unload 45% of his holdings in the days leading up to a disclosure. ***Sixth***, Defendants previously offered the contradictory argument that they made

[19] Accordingly, Riga's and Lebel's lack of pre-Class Period sales information is not exculpatory, as Defendants suggest. This is especially true for Riga, who acted as Chief Commercial Officer before he became COO, and therefore should have filed Forms 4. *See* 17 C.F.R. §240.16a-3. He also did not have any sales as COO in the four months leading up to the Class Period.

the sales because they "could have been engaged in estate planning, financial diversification, or preparing for [their] retirement." ECF 55 at 22.

c. Financings Motivated Defendants to Inflate the Price of Spectrum Common Stock

During the Class Period, Spectrum further capitalized on periods of information imbalance by engaging in public financings. ¶¶277-280. These financings motivated Defendants to maintain investor morale and elevate the Company's stock price. A financing establishes motive to commit fraud when it is "necessary to ensure that [the company] would not run out of cash and could fund ongoing operations." *In re Ibis Tech. Secs. Litig.*, 422 F. Supp. 2d 294, 317 (D. Mass. 2006); *see also Flynn v. Sientra, Inc.*, 2016 WL 3360676, at *15 (C.D. Cal. June 9, 2016) (finding motive "to conceal the contamination at the Silimed plant from investors so that they could raise enough money in the SPO to keep Sientra afloat" strengthened inference of scienter); *Howard v. Everex Sys. Inc.*, 228 F.3d 1057, 1064 (9th Cir. 2000) (finding "motive to inflate sales to raise financing"); *Nguyen v. Radient Pharms. Corp.*, 2011 WL 13141630, at *6 (C.D. Cal. Oct. 26, 2011) (motive to "help raise additional financing" indicative of scienter).[20] Throughout the Class Period, Spectrum burned through cash without earning revenue. ¶50. CW-2 explained that "[t]he survival of the Company depended on the drug [Pozi] getting approved." ¶46. Defendants suspiciously launched financings during periods when their false statements inflated the price of Spectrum common stock. On April 5, 2019, less than a month after receiving Cohort 1 results, Spectrum launched its first at-the-market ("ATM") financing during the Class Period, in which it sold new shares of Spectrum common stock to the public for market prices. ¶278. On July 30, 2020, less than four weeks after receiving Cohort 3 data, Defendants launched a secondary public offering that raised approximately $61.1 million from sales of Spectrum common stock. ¶279. On November 6, 2020, two days after Turgeon assured investors that he was "really confident" in Spectrum's future, the Company launched a third ATM financing. ¶¶206, 278.

[20] Defendants' cases are in accord. In *In re Sorrento Therapeutics, Inc. Sec. Litig.*, 97 F.4th 634, 638 (9th Cir. 2024), the court never discussed whether financings support scienter. And in *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981 (9th Cir. 2009), the court found no strong inference of scienter from financings, but unlike here, the company did not have an existential need for cash.

d. Other Indicia of Scienter

Turgeon's and Gustafson's suspicious departures and signatures on SOX certificates also contribute to a finding of scienter. *In re Fibrogen, Inc.*, 2022 WL 2793032, at *25 (N.D. Cal. July 15, 2022) ("abrupt resignation tends to support scienter and may be considered together with other allegations"); *Stocke v. Shuffle Master, Inc.*, 615 F. Supp. 2d 1180, 1190-91 (D. Nev. 2009) (finding SOX certifications were probative of scienter).

In sum, Plaintiff's allegations, "taken collectively, give rise to a strong inference of scienter" that is "at least as compelling as any opposing inference." *Tellabs*, 551 U.S. at 322-24. Defendants' benign alternative to Plaintiff's theory falls short. Defendants suggest they "amassed raw and complicated data," "submitted that data for review" by third parties without reviewing it themselves for several months, and always held "honest optimism" that Pozi would be approved. MTD at 26. But this theory raises more questions than it answers. Why did Defendants choose to make ZENITH20 an open trial if they did not plan to look at the data? What was "raw and complicated" about data that included final conclusions from radiologists concerning the efficacy of the drug for each patient? Why did insiders from a participating clinic and inside Spectrum provide corroborating accounts describing a comprehensive database available to Spectrum personnel? Why did Lebel comment on the data in internal meetings? Why did Turgeon and Riga reference response rate data before it was public? Why did Lebel say "obviously we're looking at the data" later in the same clinical trial? Why did Turgeon sell half of his shares in the weeks leading up to the announcement of the Cohort 3 failure? Defendants have no answers.

C. Plaintiff Pled Misstatements Concerning Rolontis Manufacturing

Defendants also made materially false and misleading statements or omitted material information regarding Rolontis, including: (1) Spectrum's decision to withdraw its BLA on March 15, 2019; and (2) the Hanmi manufacturing facility's readiness for FDA inspection.

1. Defendants Misled Investors About the BLA Withdrawal

On December 27, 2018, Spectrum announced its first submission of the Rolontis BLA to the FDA, which included a description of the Hanmi facility in South Korea that manufactured the drug.

¶136. The FDA forced Spectrum to withdraw its BLA application for Rolontis on March 15, 2019. ¶137. Turgeon later admitted on August 12, 2021 that the FDA "told us, look[,] in this form we wouldn't accept it, so you can wait for us to not accept that or you could voluntarily fix this stuff and resubmit." ¶228. Spectrum withdrew the BLA only to avoid the FDA's imminent rejection.

Throughout the Class Period, Defendants falsely claimed that Spectrum unilaterally chose to withdraw the Rolontis BLA and never disclosed the FDA's ultimatum. *See* ¶¶225-226, 229-232. On September 11, 2019, Turgeon told investors Spectrum withdrew the application to fix "formatting issues," to finish "translating things" from Korean to English, and to fix "tabling and things." ¶225. Two months later, on November 7, 2019, Turgeon assured investors that "***we voluntarily withdrew our BLA application earlier this year***." ¶226. The Company parroted the same misstatement on March 15, 2019 (press release (¶229)); May 9, 2019 (Form 10-Q (¶230)); August 9, 2019 (Form 10-Q (¶231)); and November 7, 2019 (Form 10-Q (¶232)).

Defendants claim they adequately disclosed the ultimatum because they told investors the withdrawal "'was the result of the company needing more time to provide certain additional manufacturing related information.'" *See* MTD at 27. But this statement maintained it was ***Spectrum's*** decision – not the FDA's – to withdraw, and therefore "did not reflect the actual state of [Defendants'] affairs at the time the statements were made." *Glazer*, 63 F.4th at 767.

The SAC details Defendants' scienter. ***First***, and most importantly, Turgeon admitted after the Class Period that the FDA forced Spectrum to withdraw the application. ¶228. *Middlesex Ret. Sys. v. Quest Software Inc.*, 527 F. Supp. 2d 1164, 1189 (C.D. Cal. 2007) ("Under Ninth Circuit precedent, a 'later statement may suggest that a defendant had a contemporaneous knowledge of the falsity of his statement, if the later statement directly contradicts or is inconsistent with the earlier statement.'"). ***Second***, Defendants repeatedly expressed their personal involvement in interactions with the FDA. In November 2018, Riga announced "a positive pre-BLA meeting with the FDA." ¶145. And on May 9, 2019, shortly after the failed first submission, Turgeon said the FDA "told us exactly what they want" in an amended BLA. ¶255. Defendants' expressions of knowledge support an inference of scienter. *See OSI*, 2015 WL 1985562, at *12; *Washtenaw*, 2012 WL 3835078, at *3.

Defendants' stock sales also underscore their scienter. Just after wrongly classifying the withdrawal as "voluntary," Turgeon unloaded 9% of his Spectrum common stock in a series of two transactions on May 16, 2019 and June 6, 2019. ¶154. And between March 25, 2019 and April 1, 2019, Gustafson sold over 15,000 shares of stock. ¶259. Sales designed "'to maximize the personal benefit from undisclosed inside information'" support a strong inference of scienter. *Am. W.*, 320 F.3d at 940.

Finally, the ATM offering Spectrum initiated from April 5, 2019 to March 2, 2020 motivated Defendants to misclassify the BLA withdrawal as voluntary. *See, e.g.*, *Everex Sys.*, 228 F.3d at 1064. Defendants' misrepresentations preserved the Company's ability to raise much-needed capital.

Defendants ignore these scienter allegations, and offer nothing but the alternate theory that "Defendants intended to accurately describe the withdrawal." MTD at 28. This argument does not explain why Turgeon waited until after the Class Period to tell the whole truth. Even so, "if two possible inferences – one fraudulent and the other nonfraudulent – are equally compelling, a plaintiff has demonstrated a strong inference of scienter." *ESG Cap.*, 828 F.3d at 1033.

2. Defendants Misled Investors About the Factory's Readiness

Spectrum submitted an amended Rolontis BLA on October 24, 2019, with a revised description of the Hanmi facility that satisfied the FDA's requirements. ¶¶140, 232. Accordingly, as the next step in the FDA approval process, the agency would inspect the facility to ensure it comported with the description in the BLA and complied with FDA requirements. ¶63. By the end of 2019, Defendants knew the Hanmi facility would not pass FDA inspection. CW-2, an executive who reported to Lebel at the time, explained that Spectrum lacked control over the facility, which had a host of deficiencies including faulty equipment, inadequate processes, and improper cleaning procedures. ¶¶44, 135, 142, 240, 245. As CW-2 put it, "the quality of plants and people [at Hanmi] were not up to industry standards." ¶44. CW-2 further explained that Spectrum had conducted and "failed [the mock inspections] a couple of times" by September 2020. *Id.* Defendants also repeatedly expressed intimate knowledge regarding the FDA's expectations and requirements for the

facility (*e.g.*, "***we are aligned with the FDA***" (¶241); "we've had a productive dialogue with the FDA [and] ***[w]e implemented their guidance***" (¶247)).

Despite their knowledge to the contrary, Turgeon and Lebel made several materially false and misleading statements boasting the readiness of the Hanmi facility leading up to the inspection. *See* ¶¶236-239, 242-244. "[A] company's decision to boast sweepingly does not operate to truncate its duty to disclose. Rather, it extends it." *Salzman*, 2024 WL 3100274, at *7. For example, on November 4, 2020, Turgeon falsely claimed the Hanmi facility was "prepared for the inspection" due to "outside experts we've hired to . . . not only run these mock inspections, but also help the readiness." ¶236. A month later, on December 22, 2020, Turgeon reiterated: "The facility has been through multiple mock inspections. . . . We have Spectrum people on the ground at the plant." ¶237. On the Company's Q4 2020 earnings call on March 30, 2021, Lebel confirmed: "We and our partner, Hanmi, are ready for the FDA pre-approval plant inspection that has been scheduled for May." ¶243. And on the Company's Q1 2021 earnings call on May 13, 2021, Turgeon stated: "Hanmi's world-class facility is ready for this inspection." ¶238.

In *Salzman*, a highly analogous case from last week, the court found nearly identical FDA-readiness statements actionable. The Court found "a strong inference that [defendant company] and its leadership – the [i]ndividual [d]efendants – were well aware of the persistent manufacturing issues" based on a single "mock inspection" that revealed persistent deficiencies. 2024 WL 3100274, at *11.[21]

Defendants contend that their statements were technically true. MTD at 29 ("There is no allegation these experts were not hired, that these inspections did not occur, nor that Spectrum personnel were not 'on the ground' to assist with the preparations."). But "the Ninth Circuit specifically has held that "'[s]ome statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors.'"" *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 512 (9th Cir. 1991). Here, while it might be technically true that Spectrum

[21] Defendants' primary case, *Aramic LLC v. Revance Therapeutics, Inc.*, 2024 WL 1354503 (N.D. Cal. Apr. 2, 2024), is readily distinguishable from *Salzman* and the present case because defendants in *Aramic* had "not yet determined" the manufacturing problem when they made the alleged misstatements. *Id.* at *10.

conducted mock inspections, Defendants failed to disclose the material fact that the facility ***failed*** those mock inspections, which ***revealed several deficiencies Spectrum did not have the power to remediate***. *See* ¶¶240-241, 245. Defendants cannot tout positive information regarding the preparation process without disclosing adverse material information they discovered. *Salzman*, 2024 WL 3100274, at *8 ("nondisclosure [of issues at the manufacturing facility] made statements about established compliance [with FDA requirements] and robust quality oversight, misleading").

Defendants also attempt to discount CW-2's credibility based on his position within the Company. But the SAC details the basis for CW-2's knowledge: He/she was an executive at a two-product Company, and explained that the failed mock inspections were "common knowledge" inside Spectrum. ¶¶241, 247. For CWs, "it is not necessary that the source have personal firsthand knowledge in a strict evidentiary sense[,] [r]ather, the source must be . . . reasonably reliable." *In re LDK Solar Sec. Litig.*, 584 F. Supp. 2d 1230, 1243 (N.D. Cal. 2008). Here, because CW-2 is particularly described by job description or responsibility, and duration of employment, his/her reliability and personal knowledge is sufficiently established. *Quality*, 865 F.3d at 1145. Moreover, Spectrum's lack of readiness is corroborated by the CRL the FDA issued, which found rampant, fundamental deficiencies at the Hanmi facility. *See In re Am. Apparel, Inc. S'holder Litig.*, 2013 WL 10914316, at *14 (C.D. Cal. Aug. 8, 2013) (company "repeatedly stated that it had made 'diligent efforts' to ensure compliance" but subsequent violations made it "it implausible to conclude that these statements were not false when made").

Defendants also assert that CW-2's statements cannot support scienter because he/she left the Company two months before the first alleged misrepresentation. MTD at 30. But CW-2 worked at Spectrum during the relevant period, *i.e.*, when the failed mock inspections occurred. *See NVIDIA*, 81 F.4th at 939; *see also Cullen v. RYVYL Inc.*, 2024 WL 898206, at *16 n.8 (S.D. Cal. Mar. 1, 2024) ("there is no rule that confidential witnesses must have been employed during the class period at all, let alone for the whole time"); *Quality*, 865 F.3d at 1145 (though CW "was not at [the company] during the Class Period" his personal knowledge supported scienter).

a. The Alleged Statements Are Not Protected by the PSLRA's Safe Harbor

None of the statements concerning the Hanmi inspection are forward-looking, as each expressed current or past facts regarding the readiness of the facility without disclosing known deficiencies. *See, e.g.*, ¶236 ("[w]e ***are absolutely ready*** for this inspection"); ¶237 ("***[w]e have Spectrum people on the ground at the plant***"); ¶242 ("***we have conducted multiple mock inspections***"); ¶243 ("[w]e and our partner, Hanmi, ***are ready*** for the FDA pre-approval plan inspection"). "'[T]o the extent Plaintiffs . . . challenge Defendants' alleged ***omission of present facts*** with respect to the challenged statements, the PSLRA's safe harbor does not apply.'" *STAAR*, 2016 WL 6699284, at *10 (some alteration in original).

Spectrum's boilerplate, generalized warnings do not address the known deficiencies or failed inspections, so they do not entitle Defendants' statements to safe harbor protection. *See, e.g.*, MTD at 31; *see also Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 947 (9th Cir. 2005) (to warrant dismissal "'reasonable minds could not disagree that the challenged statements were not misleading'").[22]

Finally, Defendants ***admitted*** knowledge regarding the FDA's expectations and the mock inspections. ¶¶36-44; *N.Y. Hotel Trades Council & Hotel Ass'n of N.Y. City, Inc. Pension Fund v. Impax Lab'ys, Inc.*, 843 F. App'x 27, 32 (9th Cir. 2021) (actual knowledge adequately pled where individual defendant "repeatedly stressed his 'intimate knowledge' of Impax's pricing strategy, models, and forecasts").

b. The Alleged Statements Are Not Inactionable Opinions

Defendants claim immunity from liability for five statements about the Hanmi preparation that they prefaced with the phrase "we believe" or "we really feel." MTD at 31 (citing ¶¶236-237, 239, 243-244). But "[s]imply inserting the word 'believe' in front of a statement of fact does not, therefore, immunize Defendants from liability." *STAAR*, 2016 WL 6699284, at *9. Opinion

[22] Defendants' cases do not help their cause. *In re Allied Nev. Gold Corp.*, 2016 WL 4191017, at *10 (D. Nev. Aug. 8, 2016) (company disclosed underlying problem at issue in forward-looking statements); *Aramic*, 2024 WL 1354503, at *5 (cautionary language associated with FDA site inspection included exact alleged basis for shortfall).

statements are still actionable when defendants do not honestly believe the stated opinions at the time they were made. *See Omnicare*, 575 U.S. at 184-86.

c. Plaintiff Pled a Strong Inference of Scienter Regarding the Hanmi Statements

The strong inference of scienter for the Rolontis statements is established by Defendants' admitted knowledge, the core operations doctrine, Defendants' stock sales, and Spectrum's intra-Class Period financings.

Admitted Knowledge. Turgeon and Lebel repeatedly described the mock inspections of the facility and Turgeon touted the fact they had "Spectrum boots on [the] ground" at the manufacturing site. ¶¶236-242. Defendants' decision to mention mock inspections, but withhold information about failed inspections, further establishes a strong inference of scienter. *See, e.g.*, *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1130 (C.D. Cal. 2005) (defendants' "failure to report serious injuries and other incidents attributed to STAAR products" raised a "strong inference" of defendants' "'actual knowledge'" that their rosy statements regarding a facility inspection were false when made).

The "'temporal proximity' of the [misstatements] and the subsequent disclosure[s]" also indicates "that defendants knew about the [problem] when they made the statement." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 988 n.5 (9th Cir. 2008); *see also Reese*, 747 F.3d at 575 ("three to six months" between "the statements and the contradictory disclosures" supports scienter). Turgeon and Lebel made false and misleading statements regarding the readiness of Hanmi on May 13, 2021, ***less than two weeks*** before the inspection began. ¶¶244, 248.[23]

Core Operations. Defendants do not dispute that the Hanmi factory – which manufactured ***both*** of Spectrum's products – was of critical importance to Spectrum's core operations. ¶¶271-273. CW-2 confirmed that the Company's financial welfare depended on commercializing Rolontis. ¶273. And on November 8, 2020, Lebel admitted "we're obviously very focused on our late assets [Pozi and Rolontis]." ¶272. It is "absurd to suggest" that Defendants would not know the status of

[23] Defendants ignore this close proximity and argue that Plaintiff relies on allegations from "two years before the inspection." MTD at 32.

the facility. *See Mulligan v. Impax Lab'ys, Inc.*, 36 F. Supp. 3d 942, 970 (N.D. Cal. 2014) ("given the importance of manufacturing and quality control to the success of Impax and the fact that both areas of operation had been flagged by the FDA, it is a logical, and strong, inference that the defendants were aware of the alleged severe and pervasive problems in Impax's Hayward facility"); *see also Hatamian v. Advanced Micro Devices, Inc.*, 87 F. Supp. 3d 1149, 1163 (N.D. Cal. 2015) (finding that a product was "critical" to the defendant's "financial success" contributed to an inference of scienter); *Shapiro v. Matrixx Initiatives, Inc.*, 2011 WL 13047298, at *6 (D. Ariz. Sept. 26, 2011) (scienter adequately pled based on "Zicam's importance to the company's business").

Stock Sales. On March 16, 2021, after touting Hanmi's readiness for the FDA's inspection for over four months, Turgeon announced that "the FDA informed us that they will be conducting a pre-approval inspection of the ROLONTIS manufacturing facility in May." ¶263. The impending inspection prompted a massive sell-off from all Defendants. *Id.* ***That same day and the day prior,*** Turgeon sold over 68,000 shares (***his second-largest sale ever***); Lebel sold over 41,000 shares (***his largest sale ever*** of 18.6% of his holdings); Gustafson sold over 36,000 shares (***his largest sale ever***); and Riga sold over 42,000 shares (***his second-largest sale ever***). *Id.* The suspicious timing and amount of these sales underscores Defendants' scienter.

Company Financings. Turgeon and Lebel made false and misleading statements regarding the readiness of the Hanmi facility on November 3, 2020. *See* ¶¶236, 242. Two days later, Spectrum initiated a third ATM offering that would continue through the end of the Class Period. ¶52. Through this ATM offering, the previous two initiated during the Class Period, and the underwritten public offering announced on July 30, 2020, Spectrum raised ***$113.7 million***. ¶¶279-280. Defendants' motive to raise this much-needed capital through a series of opportunistic offerings also supports the already strong inference of scienter.

Defendants' competing theory, that they "honestly believed . . . the Hanmi plant would be ready for the inspection" (MTD at 33) does not explain why they failed multiple mock inspections, concealed those failures, and ultimately presented the FDA with a manufacturing plant riddled with

"equipment failures," "recurring root causes of batch failures," a "deficient" understanding of manufacturing processes, and inadequate "cleaning procedures." MTD at 33; ¶142.[24]

IV. CONCLUSION

For the reasons set forth above, Plaintiff has satisfied all applicable pleading standards and Defendants' motion to dismiss should be denied in its entirety.

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Respectfully submitted,

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[24] Plaintiff's §§20(a) and 20A claims should survive because Defendants do not challenge them other than for failure to plead the primary §10(b) claim. MTD at 35.